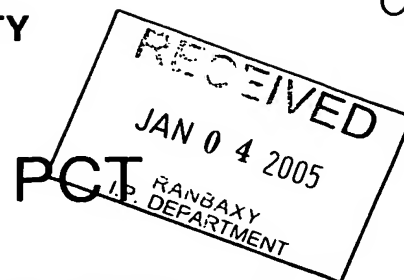


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/002191

International filing date (day/month/year)
01.07.2004

Priority date (day/month/year)
01.07.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/7048, A61K9/00, A61K9/20

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/002191

IAP20 RECEIVED TO 22 DEC 2005

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. II Priority

1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 33 with respect to industrial applicability

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 33 with respect to industrial applicability
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------------------------|
| Novelty (N) | Yes: Claims | 5,6, 12,13, 23-25 |
| | No: Claims | 1-4, 7-11, 14-22, 26-33 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-33 |
| Industrial applicability (IA) | Yes: Claims | 1-32 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/IB2004/002191

IAP2003-01-01 TO 22 DEC 2003

Re Item III.

Claim 33 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE,
COLUMBUS, OHIO, US; "Azithromycin tablet compositions" XP002308007
retrieved from STN Database accession no.
135:200437
D2 : WO 02/10181 A (BANON PARDO GABRIEL ; GELPI VINTRO JOSE
MARIA (ES); SINT QUIMICA SA (E) 7 February 2002 (2002-02-07)
D3 : EP 0 984 020 A (APOTEX INC) 8 March 2000 (2000-03-08)
D4 : WO 03/032922 A (KHONDO LEV ; LESSEN TANIA (CA); SCHWARZ
JOSEPH (CA); MATHIVANAN MATHI) 24 April 2003 (2003-04-24)
D5 : EP 0 582 396 A (PFIZER) 9 February 1994 (1994-02-09)
- 2 Document D1 discloses the preparation of tablets comprising azithromycine monohydrate. The definition of premix used in the claims of the present application cannot differentiate the preparation of the present application from the prior art.
Consequently, the subject-matter of claims 1-4, 6-11, 15-18, 33 is not new over D1.
- 3 Document D2 discloses compositions of azithromycine monohydrate and excipients (see D2, page 10, l. 1-5).
Consequently, the subject-matter of claims 1, 19 and 33 is not new over D2.
- 4 Document D3 discloses compositions of azithromycine monohydrate and excipients (see D3, claim 9).
Consequently, the subject-matter of claims 1, 19 and 33 is not new over D3.

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5 Document D4 discloses the preparation of compositions of azithromycine monohydrate (see D3, claim 7 and the examples).
Consequently, the subject-matter of claims 1-4, 7-11, 14-22, 26-33 is not new over D4.

6. The documents D1, D2, D3, D4 and D5 appear to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). These documents solve indeed the same problem, namely making composition of azithromycine monohydrate, so that, as far as novel subject-matter is concerned, the present application does apparently not fulfill the requirements of Article 33(3) PCT over these prior art documents.

Therefore, as no unexpected effect for the present composition (as far as novel) over the prior art compositions has been demonstrated, this composition does apparently not fulfill the requirements of Article 33(3) PCT.

7. For the assessment of the present claim 33 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI

Certain documents cited

Certain published documents

| Application No Patent No | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|-----------------------------|--------------------------------------|---------------------------------|---|
| WO2004035063 (E1) | 29.4.2004 | 16.10.2003 | 17.10.2002 |
| WO200400865 (E2) | 31.12.2003 | 18.6.2003 | 20.6.2002 |
| WO2003053399 (E3) | 3.7.2003 | 9.12.2003 | 21.12.2002 |

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INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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| | | | |
|-------------------|----------|-----------|------------|
| WO2003063838 (E4) | 7.8.2003 | 20.1.2003 | 1.2.2002 |
| WO2003053416 (E5) | 3.7.2003 | 9.12.2002 | 21.12.2001 |

The contents of documents E1-E5 will have to be taken in consideration for the judgement of novelty in the regional phase:

- E1 is relevant for the novelty of claims 1-4, 7,8,10, 15-22, 24-26, 28-33
- E2 is relevant for the novelty of claims 1-4, 8-22, 26-33
- E3 is relevant for the novelty of claims 1-4, 6-11, 14-22, 24-33
- E4 is relevant for the novelty of claims 1-4, 6-22,26-33
- E5 is relevant for the novelty of claims 1-4, 6-22, 26-33